Health Canada Santé Canada

Your health and safety... our priority. *Votre santé et votre sécurité... notre priorité.*

Regulatory Directive DIR2013-02

Notification/ Non-notification

(publié aussi en français)

15 April 2013

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6604-E2
Ottawa, Ontario K1A 0K9

Internet: pmra.publications@hc-sc.gc.ca
healthcanada.gc.ca/pmra
Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
pmra.infoserv@hc-sc.gc.ca

Canada

ISSN: 1197-7396 (print)
1498-5926 (online)

Catalogue number: H113-3/2013-02E (print version)
H113-3/2013-02E-PDF (PDF version)

© Her Majesty the Queen in Right of Canada, represented by the Minister of Health Canada, 2013

All rights reserved. No part of this information (publication or product) may be reproduced or transmitted in any form or by any means, electronic, mechanical, photocopying, recording or otherwise, or stored in a retrieval system, without prior written permission of the Minister of Public Works and Government Services Canada, Ottawa, Ontario K1A 0S5.

Table of Contents

1.0 Introduction 1
1.1 Purpose 1
1.2 Background 1
1.3 Highlights of Changes 1
1.4 Provisos 2
2.0 Notification 2
2.1 Documentation Requirements 3
2.1.1 Changes to Labels 3
2.1.2 Changes to Statement of Product Specifications (SPS) 3
2.1.3 Registration of Repackaged-Relabelled Products (Repack-Relabels) 4
2.1.4 Others 4
2.2 Implementation of Changes by Registrants 4
3.0 Notifiable Label Changes 5
3.1 Changes to the Registrant's Address, Regulatory Mailing Address or the Name or Address of the Canadian Agent 5
3.2 Changes to Packaging and Related Statements 5
3.3 Product Name Change 5
3.4 Deleting a Use 6
3.5 Disposal Statements 6
3.6 Trade Label Statement 6
3.7 First Aid Statements 6
3.8 Treated Paper with Food Contact Advisory Statement 7
3.9 Resistance Management Statement 7
3.10 Product Composition Statements 7
3.11 Addition of a Tank Mix That Is Currently Labelled on the Tank Mix Partner 8
3.12 Addition of Marketing Text to the Principal Display Panel 8
3.13 Translation Corrections 8
3.14 Disclosure Labelling for List 1 Formulants 9
3.15 Formulation Containing Ozone-Depleting Formulants Governed by the Montreal Protocol (except TCE) 9
3.16 Pest Control Products Containing Common Allergens 9
3.17 Effects on Treated Objects or Sites 9
3.18 Refillable Container 10
3.19 Container Size Changes / Changes in Net Contents 10
3.20 Obsolete Label Information 10
4.0 Formulation/Specification-related Changes 11
4.1 Change in Formulation Process 11
4.2 Change in Nominal Concentration of Formulant 11
4.3 Change in Certified Limits of Formulant 11
4.4 Change of the Supplier of a Formulant 12
4.5 Change in the Identity of a Formulant / Formulant Substitution (Where Concentration Does Not Change) 12

4.6 Change/Addition of Formulator Name or Address for End-Use Products and Manufacturing Concentrates Only ... 12
4.7 Change of Colourants ... 12
4.8 Change of Fragrances ... 13
4.9 Change in the Source of Technical Grade Active Ingredient for an End-Use Product or Manufacturing Concentrate ... 13
4.10 Removal of a Source of Active Ingredient ... 14
4.11 Deletion of a Formulation ... 14
4.12 Deletion of Alternate Formulant(s) ... 14
4.13 Change in the pH Range ... 14
4.14 Guarantee Change from Minimal to Nominal Concentration ... 14
5.0 Repackaged-Relabelled Products (Repack-Relabels) ... 14
5.1 Registration of Repack-Relabels ... 14
5.2 Repack-Relabel product changes ... 15
6.0 Other Notifiable Changes ... 15
6.1 Upgrade to Master Product Status ... 15
6.2 Removal of Initial Product Status ... 16
6.3 Other Potential Notifiable Changes ... 16
7.0 Non-notification ... 16
7.1 Correction of Typographical or Print Errors on Marketplace Labels ... 16
7.2 Changes in Net Content ... 16
7.3 Changes to Non-mandatory Label Elements ... 17
7.4 Label Format ... 17
7.5 Notice to User Statement ... 17
7.6 Symbols or Graphics (Pictograms And Drawings) Consistent With Label Text ... 17
7.7 Redundant Labelling Statements ... 18
7.8 Changes in Source of Starting Materials that Are Commodity Chemicals ... 18
7.9 Recycled Packaging ... 18
7.10 Non-pesticidal Characteristics ... 19
7.11 Unlabeled Tank Mixes ... 19
7.12 Buffer Zone Calculator Reference ... 20
List of Abbreviations ... 21
Appendix I ... 23
Table A Product Changes Described in this Regulatory Directive (Applicable Section of this Directive in Parenthesis) ... 23

1.0 Introduction

1.1 Purpose

The purpose of this document is to communicate to industry and other interested parties revisions to the Pest Management Regulatory Agency's (PMRA) Notification/Non-notification Policy that streamline and expand the changes to registration that can be made through these processes. This directive supersedes Regulatory Directive DIR2001-04, *Notification/Non-notification*.

1.2 Background

Since 1994, the PMRA has provided a mechanism whereby certain minor changes to registered products do not require an application for an amended registration, but may be made through simplified processes known as notification (the PMRA must be notified) or non-notification (the PMRA does not need to be notified).

The Notification/Non-notification Policy was first revised in 2001, expanding the changes that could be made through these processes. This latest revision includes further changes that can be made through notification/non-notification, streamlines the notification process, clarifies previous provisions, and eliminates those that became redundant with the changes to the *Pest Control Products Act* and Regulations.

In revising the Notification/Non-notification Policy, the PMRA examined similar programs in other jurisdictions, including the United States, United Kingdom and Australia, as well as other Health Canada regulatory programs, and consulted with industry.

The PMRA is confident that the changes in this directive will improve efficiencies for registrants and the Agency, while maintaining the Agency's mandate to protect human health and the environment.

The Agency is also committed to ongoing review and analysis of its submission policies. As further product changes deemed appropriate for notification or non-notification are identified, the PMRA will strive to keep the policy evergreen.

1.3 Highlights of Changes

Changes that are reflected in this directive include:

- expansion of the types of label changes that may be done through notification/non-notification;
- expansion of allowable notifiable/non-notifiable changes to container size;
- added provision for registration of "repack-relabel" products;
- expansion of the types of formulation-related changes that may be done through notification;
- development of an electronic standardized notification form;

- removal of references to transfer of ownership as this is now done through an administrative process, as described in Regulatory Directive DIR2005-02, *Administrative Process for a Change in a Registrant's Name or a Change in Registrant for Pest Control Products*;
- removal of the non-notifiable change to add a warranty statement as the statement is now obsolete.

1.4 Provisos

The PMRA will not process any notification requests if there are data protection implications. The regulations for the protection of test data were published in *Canada Gazette* Part II on 23 June 2010, and can be found at http://gazette.gc.ca/rp-pr/p2/2010/2010-06-23/html/sor-dors119-eng.html.

Based on the outcome of a re-evaluation, special review or new policy implementation, there may be situations where new labelling, specification-related or other requirements that would be appropriate for notification or non-notification are identified, but not covered within the provisions of this directive. In those cases, the regulatory documents outlining the new requirements will indicate how the registration changes are to be implemented (i.e., whether the changes are notifiable or non-notifiable or whether an application for amended registration is required).

There also may be circumstances resulting from a special review, re-evaluation or identification of required label corrections, where due to the number of products affected and the urgent nature of the situation, the PMRA may proactively update the PMRA's label of record and notify registrants of this action. It is the responsibility of registrants to ensure that these label revisions are incorporated into the marketplace labels within the specified timeframes or, where no timeframes are provided, at the earliest opportunity.

For changes to registration not identified in Sections 2 through 6 (Notification) or Section 7 (Non-notification) of this directive, or indicated in other PMRA regulatory documents as being notifiable or non-notifiable changes, registrants must continue to submit an "Application for Amended Registration." All such amendments require review and approval by the PMRA before sale of the product.

Any changes to product registrations through notification or non-notification may be audited during the review of subsequent applications.

2.0 Notification

Notifiable changes are those that may be made to registered pest control products upon submission to the PMRA of a completed notification form.

2.1 Documentation Requirements

The documentation requirements for eligible notification submissions are outlined below by category of change. Details on the specific changes that can be made by notification within each category, and any other documentation requirements, are described in Sections 3–6. In all cases the notification form must be completed. Registrants/applicants must also sign the declaration on the form attesting that no changes have been made to the product other than those described on the form, and those identified on the submitted label/Statement of Product Specifications Form (SPSF), that the information provided is complete and accurate, and that the criteria/conditions listed in the directive have been met. For guidance on submitting documents to the Agency, please consult the Pesticides and Pest Management portion of Health Canada's website at http://www.hc-sc.gc.ca/cps-spc/pest/registrant-titulaire/eprs-serp/index-eng.php#il.

2.1.1 Changes to Labels

Completed notification form.

Label text in MS-Word format with the notifiable changes identified using the track changes feature. Identified changes should include additions to label text as well as deletions that have been stricken. All label components should be submitted, including Emergency Registration supplemental label text (be sure to use the current approved label text). Registrants must attest that the only changes being made to the label are those which are identified. The PMRA will only verify the identified label text and, if acceptable, the full label will be posted to the Pesticides and Pest Management portion of Health Canada's website and become the current label text of record.

2.1.2 Changes to Statement of Product Specifications (SPS)

Completed notification form.

Supporting documentation, if required (for example, letter of confirmation for change in source of supply of active ingredient).

Indicate the specific change and corresponding values/units.

Completed SPSF. Changes (i.e., additions and substitutions/replacements) must be highlighted on the SPSF. Deletions to the SPSF must be indicated on the notification form. Where a product has more than one SPSF, (i.e., more than one formulation), include only the SPSFs that have changes. Indicate the formulations that are not changing on the notification form by listing the formulation and version numbers of the SPSFs that have not been submitted. Registrants must attest that the only changes being made to the SPSF are those which are highlighted on the submitted SPSF and/or indicated on the notification form. The PMRA will only verify these changes. If acceptable, these SPSFs will become the SPSFs of record.

2.1.3 Registration of Repackaged-Relabelled Products (Repack-Relabels)

Completed notification form.

Letter of confirmation and letter of authorization from the registrant of the source product.

The PMRA will use the information provided (for example, product name, registrant name and address), along with the label of the source product, to generate a label for the new repack and will issue a registration number.

NOTE: Labels and SPSFs are not to be submitted with the notification request.

2.1.4 Others

Completed notification form.

Supporting documentation as required.

2.2 Implementation of Changes by Registrants

Registrants may proceed with proposed changes once they have notified the PMRA of the change. However, the Agency will process notification requests and advise registrants, normally within 45 days from receipt of the notification submission, if the notifiable change has been accepted or not and if any subsequent action is required. If a notification request is not properly documented or is unacceptable, it will be denied.

In the case of repackaged-relabelled product (repack-relabel) requests, the PMRA must first issue a registration number before the product may be sold.

Registrants must attest on the notification form that the only changes being made to the label text or the SPSF are the ones that have been identified/highlighted. Registrants are advised that it is a contravention of the *Pest Control Products Act* to make changes to a pest control product that are not in conformance with the provisions of this directive. Where contravention does occur, appropriate corrective action will be required to bring about compliance.

Registrants are encouraged to contact the Pest Management Information Service by telephone or e-mail, as indicated on the front page of this directive, for advice about proposed changes if they are unsure of whether planned changes may be accommodated through notification or non-notification.

3.0 Notifiable Label Changes

The following label changes may be made by notification.

3.1 Changes to the Registrant's Address, Regulatory Mailing Address or the Name or Address of the Canadian Agent

Registrants are responsible for maintaining up-to-date contact information. The PMRA must be informed of any changes to the registrant's address, or the name or address of the Canadian agent. This may be done through notification. When these changes affect multiple products, the affected products may be listed on the same notification form.

3.2 Changes to Packaging and Related Statements

Changes to the shape or colour of packaging and related labelling statements are permitted by notification only if all of the following criteria are met:

- the rate, concentration, frequency or methods of application do not change;
- the proposed changes would not result in new or additional protective clothing or equipment requirements;
- precautionary statements, directions for use or other required labelling statements are not changed;
- a change in package size does not change the net contents in a way that is noncompliant with the criteria established for notifiable or non-notifiable changes to net contents outlined in this directive (refer to Sections 3.19 and 7.2).

NOTE: Changes to packaging for rodenticides, bait/control/attractant stations or other packaging that houses the pesticide during its use, or products with water soluble packaging, are not permitted through notification and require an application for new or amended registration.

3.3 Product Name Change

The name of a registered product may be changed by notification provided the registration number and registrant do not change. The new name should be specific to the product and may include a distinctive brand or trademark and the common chemical name of the active ingredient, if established. Product names cannot be the same as those of other registered pest control products. Product names that are false, confusing, misleading or make exaggerated claims will be rejected.

References to the product name on the label (i.e., in the directions for use) may also be revised through notification. For product labels that do not include references to other products (for example, tank mix partners), registrants may replace the product name with the term: "this product" by notification.

3.4 Deleting a Use

A use site and/or pest may be deleted from a product label by notification provided there remains at least one use site and at least one pest for each use site on the label. The reason for the deletion must be included as a comment on the submitted label.

3.5 Disposal Statements

Registrants may revise outdated disposal statements through notification by choosing the appropriate statement verbatim from the PMRA published standard disposal statements. The PMRA document from which the disposal statement was taken must be referenced on the notification form.

Registrants may adopt standard disposal statements for commercial and restricted class products used in agriculture and non-crop land as specified in Regulatory Directive DIR99-04, *Disposal Statements for Control Product Labels* (or most recent version) by notification This includes statements for recyclable, returnable and refillable containers.

For products for which standard statements do not apply, or where a registrant wishes to request a variation in the wording of the standard statements, changes to disposal statements must be submitted with an application for amended registration.

3.6 Trade Label Statement

The following statement specified in Regulatory Note REG2001-05, *Residue Level Label Statement*, as required on all labels of products registered for food use, including seed treatment products, may be added to a product label by notification:

"If this pest control product is to be used on a commodity that may be exported to the United States and you require information on acceptable residue levels in the United States, visit CropLife Canada's website at: www.croplife.ca."

3.7 First Aid Statements

Where the PMRA has published standard first aid statements (for example, Regulatory Directive DIR2007-01, *First Aid Labelling Statements*, or most recent version), registrants may by notification update the first aid statements as appropriate to a product by choosing verbatim the applicable PMRA published standard statements.

The PMRA document from which the first aid statement was taken should be referenced on the notification form.

3.8 Treated Paper with Food Contact Advisory Statement

For antimicrobial products used in the manufacture of paper, the label statement indicating that the pest control product cannot be used in the manufacture of paper that comes into contact with food may be removed through notification. This notification must be accompanied by a letter of no objection issued by Health Canada that clearly supports the pest control product for use on paper with food contact along with a copy of the product specifications and label text provided to support the request for the letter of no objection.

3.9 Resistance Management Statement

Resistance management statements as detailed in Regulatory Directive DIR99-06, *Voluntary Pesticide Resistance-Management Labelling Based on Target Site/Mode of Action* (or most recent version), may be added verbatim to product labels through notification provided the criteria outlined in the directive are met.

3.10 Product Composition Statements

Certain statements pertaining to product composition may be added to pest control product labels through notification as follows:

Product type

A statement identifying the product type may be added by notification. Examples of product type are: acaricide, insect repellent, insecticide, molluscicide, pheromone, rodenticide, fungicide, nematicide, pruning paint, algaecide, herbicide, adjuvant, surfactant, plant growth regulator, animal repellent, bird repellent, fish toxicant, anti-fouling paint, material preservative, sanitizer, slimicide, swimming pool algaecide, swimming pool bactericide, wood preservative.

Botanical

The term "botanical" may be added to a product label through notification if the product (i.e., active ingredient or entire product formulation) is derived from plant extracts. A botanical claim must be qualified to specify the botanical ingredient (for example, "contains X% pyrethrin, a botanical insecticide derived from the chrysanthemum flower").

Odour or fragrance

If a product formulation has been amended to add or change a fragrance, terms such as "fresh scent," "floral scent" or "lemon scent" that describe the resulting odour may be added by notification. The terms "fragrance-free" or "unscented" may be added by notification if the product is odourless or nearly odourless, and contains no odour-masking ingredients such as a perfume. The term "de-scented" may be added if the product contains an odour-masking ingredient.

Water-based

The term "water-based" may be added to a label through notification provided the product is at least 50% water by weight. All ingredients in the formulation must be in an aqueous solution (i.e., not a dispersion or emulsion), and if dilution of the product is required, the use directions must only indicate for dilution with water.

3.11 Addition of a Tank Mix That Is Currently Labelled on the Tank Mix Partner

A registrant may add through notification a tank mix to a registered product label where that tank mix already appears on the tank mix partner label.

For example, if the label for product A contains a tank mix with product B, the tank mix may be added to the label for product B through notification. The notification request must clearly indicate the exact text that is being added to the label as well as the location of text placement. The text related to the tank mix must be copied in its entirety and must be identical to that which appears on the tank mix partner label.

Once approved for the master product, a tank mix may be added to the related master copy products through notification provided the master copy label contains the uses to which the tank mix applies.

3.12 Addition of Marketing Text to the Principal Display Panel

Marketing text may be added to the principal display panel of a label provided it is consistent with the approved directions for use, the text is not false or misleading, and it does not obscure or adversely affect/impair the visibility or legibility of required label text. For example, claims pertaining to specific uses such as "For the control of bed bugs" or "Controls mosquitoes" may be added to the principal display panel of a product label, provided the claim (use) is already specified under the "directions for use" section of the label. Text that requires substantiation, (i.e., not obvious that it is consistent with the approved directions for use) may not be added through notification.

3.13 Translation Corrections

Registrants may through notification advise the PMRA of translation corrections made to the French or English label text when omissions or errors are identified.

Corrections of typographical errors on marketplace labels are non-notifiable changes. Please refer to Section 7.1 of this directive.

3.14 Disclosure Labelling for List 1 Formulants

When a formulant is recategorized to List 1, disclosure labelling may be added through notification providing that a completed notification form and appropriate supporting documentation are received by the PMRA prior to the deadline specified by the PMRA. The following statement must be added to the label in proximity to, on the same panel as, and in a type and font size comparable to, the guarantee statement:

"This product contains the toxic formulant (insert name of chemical) at (insert proportion by weight) %."

3.15 Formulation Containing Ozone-Depleting Formulants Governed by the Montreal Protocol (except TCE)

If the list of ozone depleting substances governed by the Montreal Protocol is expanded to include additional substances that are formulants, the addition of a warning on the label for a formulation containing these ozone-depleting formulants may be added through notification providing a completed notification form and appropriate supporting documentation is received by the PMRA prior to the deadline specified by the PMRA. The following statement must appear prominently on the principal display panel:

"WARNING: This product contains (insert name of chemical), which harms public health and the environment by destroying the ozone in the upper atmosphere."

3.16 Pest Control Products Containing Common Allergens

If a new allergen is identified as requiring disclosure labelling, the addition of a warning on the label of pest control products containing this allergen may be added through notification providing a completed notification form and appropriate supporting documentation is received by the date specified by the PMRA. The following statement must be added to the label in proximity to, on the same panel as, and in a type and font size comparable to, the guarantee statement:

"WARNING: contains the allergen (insert name of allergen)."

3.17 Effects on Treated Objects or Sites

When applicable to a pest control product, the following advisory statement may be added to the product label through notification:

"Users should test (treat) a small, inconspicuous area first to ensure there are no adverse effects such as staining or discolouration."

3.18 Refillable Container

Where facilities or products exist to allow for refilling, registrants may through notification add the term "refillable" to an end-use product label to indicate that the container may be refilled with the same product. The label must include a statement that indicates the container may only be refilled with the same product (for example, "The container may only be refilled with this pest control product"). Instructions for refilling the container and any purchases required for doing so (for example, purchasing a refill pouch) must also be included on the label.

3.19 Container Size Changes / Changes in Net Contents

Certain changes in net contents/container size may be added through notification as described below, provided such changes do not result in changes to use directions (*except as indicated below), mixing instructions, precautionary statements, package type, class designation or other requirements pertaining to size.

Sizes may be removed or a size range narrowed through notification.

For technical and manufacturing class products only, container sizes may be increased through notification provided any associated changes to the disposal statement would be covered by the published standard disposal statements (i.e., a standard disposal statement could be used verbatim).

Smaller container sizes may be added to any class of pest control product through notification provided the smaller size does not negatively affect the legibility of the label text, the package size is not reduced to the point that the net contents of the package are smaller than the amount required by the directions for use, and a minimum container size has not been specified by the PMRA (for example, a minimum size of 20g has been specified for capsaicin dog repellent products).

When a master product registration has been amended to change container sizes, the same changes may be made to the related master copy products through notification.

*When a container size/net contents is changed, the use directions may change to accommodate the different size provided the dilution ratio remains constant (for example, a 5 kg container to be mixed with 1,000 litres of water could be changed to a 1 kg container to be mixed with 200 litres of water).

Certain changes to container size/net contents are non-notifiable. Refer to Section 7.2.

3.20 Obsolete Label Information

Registrants may remove obsolete label information, such as references to other pest control products that are no longer registered, through notification.

4.0 Formulation/Specification-related Changes

The following changes pertaining to product formulations/specifications are notifiable.

4.1 Change in Formulation Process

A change in the formulation process may be made by notification when:

- only a blending or dilution of product components is involved;
- the nominal concentration and certified limits of the active ingredient(s) and formulants do not change; and
- the physical, chemical and biological characteristics and the performance of the product remain unchanged.

An application for amended registration is required when changes in the formulation process involve a chemical reaction or the change is beyond the scope of the parameters listed above.

4.2 Change in Nominal Concentration of Formulant

A change in the nominal concentration of a formulant may be made by notification when:

- the nominal concentration falls within the certified limits for that ingredient as listed on the accepted SPSF;
- the composition of the formulant is known to the PMRA;
- the formulant is not on the PMRA List 1; and
- the formulant does not contain contaminants of toxicologic concern.

The composition of a product must add up to 100%. Therefore, a change in nominal concentration of any given formulant must be accompanied by information on the identity and change in nominal concentration of other formulant(s), to ensure that the composition of the product adds up to 100%. The same criteria as listed above would apply to these other formulants.

4.3 Change in Certified Limits of Formulant

A change in the certified limits of a formulant may be made by notification when:

- the certified limits fall within standard certified limits;
- the PMRA has not previously determined that alternative or special certified limits apply; and
- the nominal concentration has not previously been changed by notification.

4.4 Change of the Supplier of a Formulant

A change in the supplier of a formulant may be made by notification when:

- the composition of the formulant is known to the PMRA;
- the CAS registry numbers are the same;
- the formulant is not on the PMRA List 1;
- the formulant does not contain contaminants of toxicologic concern; and
- the formulant is not proprietary (for proprietary formulants refer to Section 4.5).

4.5 Change in the Identity of a Formulant / Formulant Substitution (Where Concentration Does Not Change)

In cases where the composition of the proposed formulant is chemically similar to the formulant currently contained in the pest control product formulation, a change in formulant may be accepted through notification provided:

- the difference in composition between the proposed formulant and the current formulant is small (for example, less than 5%);
- the composition of the proposed formulant is known to the PMRA;
- the formulant or all its components are on the PMRA List of Formulants as List 2, 3 or 4 formulants or on the United States Environmental Protection Agency (USEPA) list of approved food or non-food use inert ingredients;
- the proposed formulant is not on the PMRA List 1;
- the proposed formulant does not contain contaminants of toxicologic concern; and
- the pest control product is not an antifouling paint.

4.6 Change/Addition of Formulator Name or Address for End-Use Products and Manufacturing Concentrates Only

The site of formulation for an end-use product or a manufacturing concentrate may be changed by notification, except for microbial (biological) pest control products which require an application for amended registration. Similar changes for a technical grade active ingredient, or an integrated system product (ISP) require an application for amended registration.

4.7 Change of Colourants

Change to a colourant in the form of an addition, deletion or substitution may be made through notification when:

- the total percentage of the affected colourant does not exceed 1% by weight of the formulation;
- the product is not intended for use on or mixing with seeds, and is not an antifouling paint;

- the ingredient(s) of the colourant are on PMRA List 3 or 4 or the USEPA list of approved food or non-food use inert ingredients, meet the requirements for food or drug use under the *Food and Drugs Act,* or have an appropriate USEPA exemption from the requirements of a tolerance, in which case the pesticide product containing the colourant must also meet the conditions associated with the exemption; and
- the product is not a technical grade active ingredient.

Note that pigments and dyes, while having the same function, are not considered chemically similar and cannot be substituted for each other.

4.8 Change of Fragrances

Change to a fragrance in the form of an addition, deletion or substitution may be made through notification when:

- the total percentage of the affected fragrance does not exceed 1% by weight of the formulation;
- the composition of the fragrance has been provided to the PMRA by the supplier, manufacturer or registrant;
- the ingredient(s) of the fragrance are on PMRA List 3 or 4 or the USEPA list of approved food or non-food use inert ingredients, or the USEPA Fragrance Ingredient List, or the ingredient(s) of the fragrance meet the requirements for food or drug use under the *Food and Drugs Act*; and
- the product is not a technical grade active ingredient.

4.9 Change in the Source of Technical Grade Active Ingredient for an End-Use Product or Manufacturing Concentrate

A registrant may add or change a source of the same technical grade active ingredient by notification, provided the alternate source:

- is registered for the same uses as the current source;
- contains no formulants;
- contains no impurities of toxicological concern at levels higher than are present in the current source;
- has a nominal concentration that is within the standard certified limits of the nominal concentration of the current source; and
- has a nominal guarantee and in the cases where the registrant wishes to retain the current source(s), the guarantee of the current source(s) is also nominal.

A letter of confirmation of source of supply (LOC) for the new source of technical grade active ingredient must be submitted with the notification form.

Where the addition of an alternate source results in a change in formulant proportions, the SPSF must reflect this.

4.10 Removal of a Source of Active Ingredient

A source of active ingredient may be removed from an end-use product or a manufacturing concentrate through notification provided there remains at least one registered source of active ingredient and no other changes are being made.

4.11 Deletion of a Formulation

A formulation and related label statements (for example, allergen or formulation preservative) may be deleted through notification, provided at least one current formulation remains and no other changes are being made.

4.12 Deletion of Alternate Formulant(s)

An alternate formulant(s) and related label statements may be deleted through notification provided the basic formulant remains and no other changes are being made.

4.13 Change in the pH Range

The pH range for a pest control product may be revised through notification (for example, from 7 to a range of pH 6–8) provided there is no change in the composition of the product beyond what is allowable through notification.

A material change in pH (for example, from pH 7 to pH 4) cannot be made through notification and requires an application for amended registration.

4.14 Guarantee Change from Minimal to Nominal Concentration

A guarantee change from minimal to nominal concentration may be done through notification for an end-use product or manufacturing concentrate provided:

- the source of the active ingredient (for example, technical product, manufacturing concentrate) has a guarantee expressed as a nominal concentration;
- the registrant provides the nominal concentration and the upper and lower certified limits;
- the upper and lower limits fall within the standard limits; and
- the change in guarantee does not involve an adjustment in the amount of technical product.

5.0 Repackaged-Relabelled Products (Repack-Relabels)

5.1 Registration of Repack-Relabels

A product that is a repack and a relabel of a registered pest control product (known as the source product) may be registered through notification when:

- a letter of confirmation of source of supply (LOC) indicating that the product is a repack of the source product and a letter of authorization (LOA) to copy label uses from the registrant of the source product is provided;
- the label of the repackaged product is identical to that of the source product in all aspects except for: trade dress, company name and address, product name, pest control product registration number, and Canadian contact information, as appropriate (master copies which include only a subset of the label text of a master product cannot be registered through notification and require a Category D application);
- the source product is an end-use product or manufacturing concentrate (Repack-relabels of technical grade active ingredients are not permitted through notification);
- the source product does not have conditional registration; and
- the applicant provides the name and address of the formulating (repackaging) site.

The PMRA will issue a registration number for the repack-relabel product. Labels are not to be submitted; only an identification of the label text that differs from the source product is to be included on the notification form. The PMRA will issue a text label for the repack-relabel product based on the label of the source product including the acceptable text differences.

5.2 Repack-Relabel product changes

The following changes may be made to repack-relabel products through notification:

- Changes in product trade name, trade dress, company address and Canadian contact information, as appropriate;
- Label changes to match approved amendments to the source product provided the revised repack label is identical to the revised version of the source product excluding the product name, trade dress and company address, and an LOA from the source product registrant supporting the addition of new label text (for example, new uses) is provided (for these label changes, labels are not to be submitted as the PMRA will issue an amended text label for the repack-relabel product based on the amended source product label); and
- Additions or changes to the container size to match approved amendments to the source product.

Label changes to a master copy product to match amendments to the related master product may be done through notification provided the master copy product meets the criteria of a repack-relabel product. An LOA from the master product registrant is required to support the addition of new label text that has been approved for the master product.

6.0 Other Notifiable Changes

6.1 Upgrade to Master Product Status

A pest control product's registration status may be upgraded to master product status by notification provided:

- the product is an end-use product or manufacturing concentrate (technical grade active ingredients cannot be master products);
- the product does not have conditional registration; and
- the product does not contain any unregistered active ingredient.

If the PMRA does not have a current LOC (i.e., dated within the last five years) for the active ingredient(s) used in the formulation of the product, an updated LOC must be submitted with the notification request.

6.2 Removal of Initial Product Status

The initial product status of products which have initial or combined initial master product status may be removed through notification provided there are no associated private label products registered.

6.3 Other Potential Notifiable Changes

There may be cases where certain simple minor label or specification-related changes not specified in this directive, might be appropriate for notification. In such cases, registrants should contact the PMRA to determine the appropriate mechanism for processing the changes (i.e., via notification or by submitting an application for amended registration).

7.0 Non-notification

Non-notification changes are those that can be made to a registered product without notifying the PMRA.

The following non-notifiable changes may be made to product labelling, packaging or specifications.

7.1 Correction of Typographical or Print Errors on Marketplace Labels

The correction of typographical or print errors on marketplace labels are non-notifiable.

7.2 Changes in Net Content

Certain changes in the net contents of products are non-notifiable provided such changes do not impact use directions, mixing instructions, precautionary statements, package type, class designation or other requirements pertaining to size. The net content change must fall within the range currently approved by the PMRA for the product. Where a range does not exist, the proposed change must fall between the smallest and largest size currently approved for the product.

Certain other changes in net contents may be submitted as notifiable changes (refer to Section 3.19).

7.3 Changes to Non-mandatory Label Elements

The revision, addition or deletion of the following may be made without notifying the PMRA:

- the Transportation of Dangerous Goods hazard symbols, when a shipping container is also the immediate container offered for sale;
- lot or batch codes or other production identifiers;
- date of manufacture or label approval; and
- distributor's name and address (the registrant's full name and address must remain on the principal display panel).

7.4 Label Format

Changes to label format design that do not modify approved label text and are consistent with the requirements of the Pest Control Products Regulations and information contained in other relevant PMRA guidance documents may be made without notifying the PMRA. These may include changes in label colour, company logo, type size or style, use of space, configuration, or placement of label elements. Improvements to label design, label wording and presentation of information, as outlined in Label Process Series documents LPS2011-03, *Designing Marketplace Labels of Domestic Class Pest Control Products* and LPS2011-04, *Guidance for Designing Peel-Back and Multi-Component Labels of Domestic Class Pest Control Products*, are non-notifiable.

7.5 Notice to User Statement

Where there is no Notice to User Statement on a product label, or where a previous version is currently included on the label, only the following statement may be added to the secondary display panel, as per section 26(2)(a) of the Pest Control Products Regulations without notification:

"NOTICE TO USER: This pest control product is to be used only in accordance with the directions on the label. It is an offence under the *Pest Control Products Act* to use this product in a way that is inconsistent with the directions on the label. The user assumes the risk to persons or property that arises from any such use of this product."

For domestic class products only, the Notice to User Statement may be removed from the product label without notifying the PMRA.

7.6 Symbols or Graphics (Pictograms And Drawings) Consistent With Label Text

Pictograms and drawings may be added to the product label without notification, provided that they accurately represent the instructions on the approved label, are not false or misleading, and are consistent with the provisions in Label Process Series LPS2011-03 *Designing Marketplace Labels of Domestic Class Pest Control Products* or other applicable guidance.

7.7 Redundant Labelling Statements

Redundant labelling statements may be removed without notification provided that:

- the change does not contravene labelling requirements stated in the Pest Control Products Regulations;
- the precautionary symbol(s) and statement(s) are retained, and all other requirements of the Pest Control Products Regulations are met; and
- statements specifically required by the PMRA are not removed (for example, statements such as grazing or aerial application limitations).

7.8 Changes in Source of Starting Materials that Are Commodity Chemicals

For technical products covered by PMRA Regulatory Directive DIR98-04, *Chemistry Requirements for the Registration of a Technical Grade of Active Ingredient or an Integrated System Product* (or most recent version) changes in the source of starting materials that are commodity chemicals may be made without notification if the technical grade active ingredient or integrated system product remains in accordance with the specifications upon which registration was granted. Commodity chemicals are products manufactured globally on a large scale using standardized manufacturing methods, with well-defined impurities, and are characterized and sold by nationally or internationally recognized standard specifications. Examples of commodity chemicals include, but are not limited to, sodium chloride, hydrochloric acid and acetic acid. Non-notification is acceptable, therefore, if:

- the nominal guarantee and certified limits of the active ingredient(s) are not changed;
- the upper certified limit of any existing impurity is not exceeded;
- there are no new impurities found at a level equal to or greater than 0.1% by weight; and
- impurities of toxicological significance, as described in clause 2.13.4 of DIR98-04, *Chemistry Requirements for the Registration of a Technical Grade of Active Ingredient or an Integrated System Product* are not introduced, or the current upper certified limits of such impurities currently listed in the product specifications are not exceeded.

Otherwise, a submission to amend the registration is required. Changes in the source of starting materials that are not commodity chemicals require an application for amended registration.

7.9 Recycled Packaging

A statement and/or the Mobius loop symbol reflecting the recycled content of the product packaging may be added to, deleted from or changed on, a label through non-notification provided the statement and symbol are consistent with the Canadian Standards Association June 2008 guidelines document (PLUS 14021) *Environmental claims: A guide for industry and advertisers* (or the most recent version).

7.10 Non-pesticidal Characteristics

The following non pesticidal information may be added, deleted or changed without notifying the PMRA:

"Made in Canada"

- Factual statements about where a product is made (for example, "Made in Canada" or "Product of Canada") may be added to pest control product labels provided they comply with criteria established by the Competition Bureau Canada in their publication *Enforcement Guidelines for "Product of Canada" and "Made in Canada" Claims*, published on December 22, 2009 (or most recent version).

Consumer access information

- Telephone numbers, internet addresses and emergency contact information may be added/deleted/changed. (Note: Changes to a registrant's address, regulatory mailing address and the name or address of the Canadian agent are notifiable changes. Refer to Section 3.1 of this directive.)

Price or price-related marketing

- Claims regarding price or price-related marketing such as "rebate available" and "low price" may be added/deleted/changed.

Company history

- Information pertaining to company history such as "selling insect repellents since 1952" may be added/deleted/changed.

New formulation

- Accurate statements about formulation changes (for example, "new" or "improved") that have been approved by the PMRA may be added to a product label by notification for a period of one year, from the time the new formulation is first marketed. The product attribute that is "new" or "improved" must be clearly specified (for example, "new formulation," "new scent," etc.).

7.11 Unlabeled Tank Mixes

The following standard statement may be added verbatim to the label of commercial class products (excluding adjuvants) used for crop production or vegetation management without notifying the PMRA. Registrants wishing to add a statement that differs from this standard statement must submit an application for new or amended registration.

"In some cases, tank mixing a pest control product with another pest control product or a

fertilizer can result in biological effects that could include, but are not limited to: reduced pest efficacy or increased host crop injury. The user should contact [insert registrant name] at [insert contact information] for information before mixing any pesticide or fertilizer that is not specifically recommended on this label. The user assumes the risk of losses that result from the use of tank mixes that do not appear on this label or that are not specifically recommended by [insert registrant name]."

A crop production use is directly related to the activities associated with growing a plant that is intended to be used by humans for any variety of purposes. This includes plants grown for food, feed, fibre, and ornament, among others. Tank mixes may be used for crop production uses during any stage of production (from pre-planting to post-harvest) but excludes applications during storage.

Vegetation management in the context of this notifiable change refers to the management or control of undesirable vegetation (i.e., weeds) and is limited to tank mixes that include only herbicides.

7.12 Buffer Zone Calculator Reference

The following statement may be added verbatim to a pest control product label without notifying the PMRA provided the label contains buffer zones, and the specified application methods on the label comply with the criteria for being able to use the calculator. Registrants wishing to add a statement that differs from this standard statement must submit an application for new or amended registration.

"NOTE: Applicators may recalculate a site-specific buffer zone by combining information on current weather conditions and spray configuration for the following applications: all airblast applications, and for field and aerial applications which specify the following droplet size category wording on the product label: 'DO NOT apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE) [Fine or Medium or Coarse] classification.' To access the Buffer Zone Calculator, please visit the Pest Management Regulatory Agency web site."

List of Abbreviations

EP	End-use product
LOA	letter of authorization
LOC	Letter of confirmation of source of supply
PMRA	Pest Management Regulatory Agency
SPS	Statement of Product Specifications
SPSF	Statement of Product Specifications Form
TGAI	Technical grade active ingredient
USEPA	United States Environmental Protection Agency

Appendix I

Table A Product Changes Described in this Regulatory Directive (Applicable Section of this Directive in Parenthesis)

Type of Change	Notification	Non-notification	Application for New or Amended Registration
Label Changes			
Address for registrant or regulatory mail	(3.1)		
Name and address of Canadian agent	(3.1)		
Packaging and related statements	Criteria are met (3.2)		
Product name	(3.3)		
Deleting a use	(3.4)		
Disposal statements	Using PMRA standard disposal statements (3.5)		Using non-standard statements and variations of the standard statements
Trade label statement	(3.6)		
First aid statement	Using PMRA standard first aid statements (3.7)		Using non-standard statements and variations of the standard statements
Removal of treated paper with food contact advisory statement	(3.8)		
Resistance management statement	Using PMRA standard statement (3.9)		Using non-standard statements and variations of the standard statements
Product type	(3.10)		
"Botanical"	(3.10)		
Odour or fragrance	(3.10)		
"Water-based"	(3.10)		
Addition of tank mix	Where currently labelled on tank mix partner and text is identical (3.11)		Other tank mixes or variations in label text
Marketing text	Where text is clearly consistent with approved directions for use (3.12)		Text that is not clearly supported by the approved directions for use, for example, duration of control claims
Translation corrections	For text omissions or errors (3.13)	Typographical or print errors on marketplace labels (7.1)	General "improvement" of translated text
List 1 formulant label disclosure	(3.14)		
Ozone-depleting formulant label disclosure	(3.15)		
Allergen label disclosure	(3.16)		
Effects on treated objects or sites	Using PMRA standard statement (3.17)		Other advisory statements
"Refillable" container	(3.18)		

Type of Change	Notification	Non-notification	Application for New or Amended Registration
Net contents/container size	Notification Criteria are met (3.19)	Non-notification criteria are met (7.2)	Neither notification or non-notification criteria are met
Obsolete label information	(3.20)		
Correction of typographical or print errors		(7.1)	
Non mandatory label elements		As specified (7.3)	Other non-mandatory label elements/text
Label format		(7.4)	
Notice to user statement		(7.5)	
Symbols or graphics (pictograms and drawings)		(7.6)	
Redundant label statements		(7.7)	
Recycled packaging		(7.9)	
Place of manufacture		(7.10)	
Consumer access information		(7.10)	
Price or price-related marketing text		(7.10)	
Company history		(7.10)	
"New" or "improved" formulation		(7.10)	
Unlabeled tank mix	Using PMRA standard statement	(7.11)	Changes to the standard statement
Buffer zone calculator reference	Using PMRA standard statement	(7.12)	Changes to the standard statement
Formulation/Specification-related Changes			
Formulation process	Criteria are met (4.1)		Criteria are not met
Nominal concentration of a formulant	Criteria are met (4.2)		Criteria are not met
Certified limits of a formulant	Criteria are met (4.3)		Criteria are not met
Supplier of a formulant	Criteria are met (4.4)		Criteria are not met
Identity of a formulant/ formulant substitution	Criteria are met (4.5)		Criteria are not met
Formulator name or address	For end-use products and manufacturing concentrates that are not microbial pest control products (4.6)		For all technical grade active ingredients and microbial end-use and manufacturing products
Colourants	Criteria are met (4.7)		Criteria are not met
Fragrances	Criteria are met (4.8)		Criteria are not met
Source of TGAI for an EP or MA	Criteria are met (4.9)		Criteria are not met
Removal of a source of active ingredient	(4.10)		
Deletion of a formulation	(4.11)		
Deletion of alternate formulant	(4.12)		
Change in pH range	Criteria are met (4.13)		

Type of Change	Notification	Non-notification	Application for New or Amended Registration
Source of starting material for TGAI		Criteria are met (7.8)	Criteria are not met
Guarantee conversion from minimal to nominal	For end use products and manufacturing concentrates where guarantee for technical product used is nominal (4.14)		For technical products
REPACK-RELABELS			
Registration of repack-relabels	Criteria are met (5.1)		Criteria are not met
Amendments to repack-relabels	Criteria are met (5.2)		Criteria are not met
OTHER CHANGES			
Upgrade to Master Product status	Criteria are met (6.1)		
Removal of Initial Product status	Where there are no related private label products registered (6.2)		
Other potential notifiable changes	Consult the PMRA (6.3)		